Round 7 million people in Germany currently suffer from diabetes. Globally, as many as 425 million people are affected by this widespread disease, which adds up to around 9% of the adult world population [1, 2]. The persistent high blood sugar levels of diabetics can lead to serious consecutive diseases such as strokes, heart attacks, amputations (diabetic foot), blindness and the necessity for dialysis treatments. Early diagnosis and good diabetes management are therefore indispensable.

The fact that there is a disorder in the insulin balance is the same for all diabetes diseases. Insulin is a hormone that is produced in the pancreas and stimulates body cells to absorb glucose from the blood. A basic distinction is made between different types of diabetes [3].

One speaks of type 1 diabetes when the immune system destroys insulin-producing cells and the pancreas no longer delivers insulin. Type 1 diabetes is usually genetically determined and is normally diagnosed at an early age.

If the body still produces insulin, but the cells of the muscle- and fat tissue no longer absorb the substance properly (quasi resistant to insulin), or if there is a defect in the insulin secretion, we speak of type 2 diabetes, which is normally attributed to poor nutrition and lack of exercise.

The International Diabetes Federation (IDF) estimates that one in two cases of diabetes in adults has not yet been diagnosed. Novo Nordisk, a global healthcare company, goes even further and describes a “Rule of Halves” [4]. Of the diagnosed diabetics, only about half are treated and only 50% of these receive the right amount of insulin at the right time.

Overall, the IDF expects the number of diabetics to rise by more than 50% to nearly 650 million by 2040 [2]. However, if diagnosed diabetics pay attention to their body, check their blood sugar level regularly and supply insulin accordingly, they can live with the disease quite normally. In the case of type 1 diabetes insulin must be administered, whereas type 2 may require insulin depending on the stage of the disease.

**Precision Work in the Service of Patients**

*High Performance Molds for Plastic Products in Diabetes Therapy*

Precisely, reliably and in large quantities, Schöttli AG constructs high-performance injection molds for challenging applications in medical technology. The Swiss company is currently world market leader for modern diabetes therapy in this field, from the syringe to the artificial pancreas device.
Up to now, insulin cannot be administered orally with sufficient precision, meaning that the substance must always be injected into the subcutaneous tissue. Here, the insulin must be administered to the body in smallest quantities (a few milligrams) as precisely as possible and ideally as regularly as possible. Precise measurement – or even better continuous monitoring – of the blood sugar level is an important prerequisite for this.

Precise Plastic Parts Help in Diagnosis and Therapy

Whereas about a quarter of a liter of blood was needed a hundred years ago to determine the blood sugar level, today there are already devices as small as a smartphone and test strips that use around 0.3 µl to provide a comprehensive picture of the metabolism [5, 6]. Syringes and pens allow patients to inject themselves precisely the required insulin quantities. Insulin pumps that are worn on the body and work with appropriate sensors “closed loop” go one step further [5, 7]. The step towards an artificial pancreas was tested last year for the first time.

Depending on the culture of the country and the services provided by the health insurance systems, disposable syringes or pens are preferred for insulin dosage. In Germany, for example, about 80% of all patients administer their insulin with pens, while in North America or Asia on the other hand, disposable insulin syringes account for the lion’s share of around 80%.

Disposable syringes for the administration of insulin usually consist of a cylinder with a firmly glued-in injection needle and a plunger. Here, Schöttli AG, Diesenhofen, Switzerland, offers highly productive and reliable mold solutions with hot-edge nozzles and dual side gating for syringe cylinders, syringe plungers and similar applications, usually made of polyolefins.

As an alternative to disposable syringes, high-precision so-called pens are often used today for the subcutaneous administration of insulin. These “disposable pens” consist of several precise plastic parts with a fixed insulin cartridge, with sufficient content for several treatments. Slightly more expensive, but also available are long-term pens with replaceable insulin cartridges. In any case, a new injection needle, which is screwed onto the pen-housing in conjunction with a pen-needle hub, should be used for each administration. A needle is intended for a single administration and is then disposed of together with the pen-needle hub.

A so-called pen-needle shield protects both the needle and the user from injuries immediately before and after use. For further protection and packaging, the pen needle cover is sealed with a film during transport (Fig. 1).

Advanced Components with Safety Mechanism

An advanced needle type (safety-pen-needles) is a slightly more sophisticated variant. These components are characterized by a special safety mechanism. A protective cap or shield automatically moves mechanically over the injection needle as soon as it is removed from the skin surface. This effectively prevents needle prick injuries caused by carelessness. Precisely because insulin is administered in the vast majority of cases at home, and not in doctors’ surgeries or hospitals, the ease of use and consumer protection are particularly important. Another advantage of this protection mechanism is the effective prevention of multiple use. In any case, it should be ensured that the needle is disposed of after a single use.

For the manufacture of such pen-needle-components and safety-pen-needles, molds are required that produce the needed components, usually made of polyethylene or polypropylene, in the required quantities and at the same time with the required precision. Based on many years of extensive experience, Schöttli AG is an expert in the field of...
high-cavity injection molds for medical components. For example, the Swiss company can offer corresponding single-face molds for pen-needle shields with up to 256 cavities. Pen-needle-covers and similar components are produced on stack molds with up to 192+192 cavities with highest precision and highest performance (Fig. 2). Some time ago, Schöttli delivered the world’s first 192-cavity mold for pen-needle hubs with Schöttli’s side gate hot runner technology (Fig. 3).

With these products, the needles, which protrude out of the hub on both sides, are subsequently glued in place fully automatically. This is a special challenge, as the needles have very small outer diameters of down to 34 G (34 gauge equals 0.18 mm). This requires correspondingly small cylindrical openings in the injection molded part and accordingly, enormous precision in the injection mold. Each of the 192 cavities is centered individually so that the forming pins (gauge pins) do not break. Only in this way the reliability of the molds, for which Schöttli is known, can be achieved. The resulting high level of availability and, depending on the application, unmatched number of cavities leads to a significant increase in productivity per square meter of production area for the customer.

"This is particularly important because our customers do not want to produce two to three million plastic parts per year, but two to three million a day," says Adolph Keller, Managing Director Sales & Marketing at Schöttli, "and with consistent accuracy." Here, Schöttli molds stand for maximum repeat accuracy and adherence to the tightest tolerances. This is important to ensure the high demands of the final product.

All molds for the medical components presented here are equipped with Schöttli hot runner systems. Molding is of course in a cleanroom environment normally with fully automated production surroundings. In addition to higher productivity and maximum reliability, the economic efficiency of the investment is a priority for customers worldwide. "We can certainly buy cheaper molds from other suppliers, but not molds on which we can produce our products more cheaply and reliably," says a globally active customer based in the USA.

From Pumps to the Artificial Pancreas

The various insulin pumps already available on the market today are usually worn on the body, whereby a so-called "closed-loop systems", which are precisely adapted to current requirements. Here, the blood sugar level is measured with a sensor worn on the skin (Continuous Glucose Monitoring = CGM) and transmitted wirelessly to the pump. The pump doses the right amount of insulin "closed-loop" at the right time. As in other medical fields, the classical treatment method and modern online diagnosis systems are gradually converging in diabetology. Since too much insulin can be as dangerous as too little insulin, this innovation contributes to greater patient safety and fewer complications, thus reducing the global cost of diabetes treatment.

For other diabetes applications, Schöttli AG also offers injection molds for the production of consumables such as patches, and mechanical components. The use of this technology does not stop with the insulin supply of diabetes patients. Automated administration of medication also makes sense and is therefore desirable for other diseases.